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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,167	06/15/2000	James M. Brugger	17742-002510	2793

7590

03/10/2004

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/10/2004

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,167

Applicant(s)

BRUGGER ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-8, 10-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 10, 12, 14 and 16-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, 7, 10, 12, 14, 16-21, 23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte et al (US 4,681,560).

Schulte discloses an implantable port (figs. 1 and 7) and a subcutaneous substance delivering method. The port 28 has a body with a flow passage having an upstream and downstream end, a pressure-responsive valve at 60 being integrally formed with the port body 28 and positioned in the flow passage downstream portion. The port body comprises a housing 40, and a housing insert 38. The housing insert 38 comprises a compliant material defining a portion of the flow passage.

3. Claims 1-3, 5, 7, 10, 14, 16-23, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Utterberg.

Utterberg discloses an implantable port (figs. 1 -3) and a subcutaneous substance delivering method. The port 10 has a body with a flow passage having an

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upstream and downstream end, a pressure-responsive valve at 44 being integrally formed with the port 10 and positioned in the flow passage downstream portion. The port body comprises a housing, and a housing insert. The housing insert comprises a compliant material defining a portion of the flow passage.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte et al in view of Utterberg (US 6,544,214).

Schulte discloses the invention substantially as claimed. However, Schulte fails to disclose the access tube being a blunt cannula.

Utterberg teaches an implantable port where the access tube has a blunt cannula to infuse fluid. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Utterberg's cannula in Schulte's implantable port. Doing so would have minimized tissue cutting in the insertion area with its non-cutting or blunt cannula.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte et al in view of Moorehead (US 6,478,783).

Schulte discloses the invention substantially as claimed. Schulte discloses the housing 40 made of silicon elastomer. However, Schulte fails to disclose the housing being made of stainless steel.

Moorehead teaches that is known to use any suitable biocompatible materials, including stainless steel, metal, or implantable grade thermoplastics on implantable ports. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schulte's port housing with any of Moorehead's suitable materials, i.e. stainless steel, since it is well known that these materials are biocompatible and non-corrosive within the body.

7. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulte et al in view of Kaplan et al (US 6,162,238).

Schulte discloses the invention substantially as claimed. However, Schulte fails to disclose the kit having instructions having the steps as claimed, and a package to contain the implantable port and the instructions.

Kaplan teaches a kit (fig. 9) including an implantable system 12,16, instructions, and a package 304 to contain the implantable port and the instructions. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Schulte's kit by including instructions and a package as evidenced by Kaplan as old and well known. Also, the instructions (descriptive material) are not functionally related to the instruments or tools of the kit (which are not even a substrate for the printed matter), and, as such, do not distinguish the invention

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from the prior art. *In re Gulack*, (CAFC) 217 USPQ 401; *In re Miller*, (CCPA) 164 USPQ 46.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


9. Please note that integrally formed has been interpreted as "put together to form an integral part".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 5, 2004


Cris L. Rodriguez
Examiner
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